

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

DR. JOSEPH CICCIO, et al.)
)
v.) No. 3:19-cv-0845
)
SMILEDIRECTCLUB, LLC, et al.)

ORDER

Pending before the Court is Defendants’ Limited Objection to the Special Master’s Order on His *In Camera* Review of Documents Produced Pursuant to Docket Entry 303 (Docket No. 325), in which Defendants object to an order entered by the Special Master requiring Defendants to produce certain previously withheld documents. (Docket No. 319.) Provider Plaintiffs have filed a response in opposition to Defendants’ objection. (Docket No. 330.) For the reasons that follow, Defendants’ objection (Docket No. 325) is OVERRULED.

ANALYSIS¹

The Court reviews procedural matters resolved by the appointed Special Master pursuant to the “abuse of discretion” standard. (Docket No. 168 at 4.) *See also* Fed. R. Civ. P. 53(f)(5) (“Unless the appointing order establishes a different standard of review, the court may set aside a master’s ruling on a procedural matter only for an abuse of discretion.”). Because a special master’s ruling on the scope of permissible discovery is considered a procedural matter, *Ravin Crossbows, LLC v. Hunter’s Mfg. Co.*, No. 5:18-cv-1729, 2020 WL 7706257, at *2 (N.D. Ohio Dec. 29, 2020), the Court reviews for abuse of discretion.

¹ A detailed description of the scope of the Special Master’s duties can be found in the Court’s appointment order (Docket No. 168.)

On December 23, 2021, the Special Master entered an order requiring Defendants to produce for *in camera* review certain documents previously withheld from Provider Plaintiffs on the basis of attorney-client privilege and the common interest doctrine. (Docket No. 303.) Following *in camera* review, the Special Master entered an order in which he found that Defendants had improperly withheld numerous documents that must be produced. (Docket No. 319.)² Defendants now object to a portion of that order, specifically the Special Master’s requirement that Defendants turn over their allegedly privileged communications with the U.S. Food & Drug Administration (“FDA”) Third Party Review Group, Ian Kitching, MRC-X, and Knoell USA. (Docket No. 325 at 2.)

Parties are permitted to obtain discovery “regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case...” Fed. R. Civ. P. 26(b)(1). A party withholding documents as privileged must establish the existence of a privilege that protects the contents of the documents by expressly making a claim of privilege, and by describing the withheld documents or communications “in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim.” Fed. R. Civ. P. 26(b)(5)(A). Questions of privilege must be assessed under federal common law in federal questions cases. *Reed v. Baxter*, 134 F.3d 351, 355 (6th Cir. 1998).

The attorney-client privilege permits a party to withhold “communications between an attorney and a client made in confidence and for the purpose of obtaining or facilitating the rendition of professional legal service.” *John Labatt Ltd. v. Molson Breweries*, 898 F. Supp. 471,

² The Special Master reviewed a sampling of 15 communications exchanged between counsel for Defendants and each third-party at issue, then issued a ruling requiring all communications between Defendants and the subject third-party – not just those reviewed *in camera* – be produced. (Docket No. 319 at 8 n.4, 12-13.; Docket No. 325 at 3 n.1.)

473 (E.D. Mich. 1995). The elements required to establish the existence of the privilege include the following:

(1) Where legal advice of any kind is sought (2) from a professional legal adviser in his capacity as such, (3) the communications relating to that purpose, (4) made in confidence (5) by the client, (6) are at his instance permanently protected (7) from disclosure by himself or by the legal adviser, (8) unless the protection is waived.

Reed, 134 F.3d at 355-56 (citing *Fausek v. White*, 965 F.2d 126, 129 (6th Cir. 1992)). Such communications may include those between a client or client representative and an attorney or the attorney's representative so long as the conditions for attorney-client privilege are met. *John Labatt*, 898 F. Supp. at 473.

The common interest doctrine, sometimes referred to as the “joint defense” rule, “is not an independent basis for privilege, but an exception to the general rule that the attorney-client privilege is waived when privileged information is disclosed to a third party.” *Broessel v. Triad Guar. Ins. Corp.*, 238 F.R.D. 215, 219 (W.D. Ky. 2006) (internal citation omitted). It assumes both “the existence of a valid underlying privilege” and that “there is a valid basis for exchanging information with a third party without undermining the requirement of confidentiality for the attorney-client privilege to apply.” *Id.* Pursuant to the doctrine, “an attorney-client privileged communication can be exchanged with the third party without waiving the privilege, provided that the parties have an identical legal interest with respect to the subject matter of the communication.” *Iafrate v. Warner Norcross & Judd, LLP*, 335 F.R.D. 378, 381 (E.D. Mich. 2020) (internal citations and quotations omitted).

The doctrine is generally applicable in three different situations, only one of which is relevant to the instant dispute: the common interest may prevent waiver of the attorney-client privilege “when two or more clients share a common legal or commercial interest and, therefore,

share legal advice with respect to that common interest.” *Id.* at 220. Notably, the doctrine applies only “to a common shared legal, rather than a common shared financial or commercial, interest.” *Id.*

Having reviewed *in camera* the documents provided to the Special Master, the Court turns to the Defendants’ specific objections.

1. FDA Third Party Review Group

The FDA Third Party Review Program is described as a mechanism that “provides medical device manufacturers with a voluntary alternative review process, in which accredited Third Party Review Organizations (3P510k Review Organizations) are allowed to review certain low-to-moderate risk medical devices” and thus help the FDA yield more rapid “510(k) decisions,” which are “premarket submission[s] made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device.”³ The manufacturer provides necessary information to the third-party review organization – in this case, FDA Third Party Review Group – which then “sends the submission to the FDA including the original 510(k) submission, the 3P510k Review Organization’s review, and a recommendation of either substantially equivalent (SE) or not substantially equivalent (NSE).” The FDA makes the ultimate 510(k) decision or SE or NSE.

The Special Master concluded that Defendant SmileDirect’s communications with FDA Third Party Review Group were not made pursuant to a common interest agreement, and that there was no indication that FDA Third Party Review Group was retained by SmileDirect for the purpose of providing legal advice. (Docket No. 319 at 7.) The Special Master found that FDA Third Party Review Group is “more akin to the FDA itself, not a consultant retained to provide

³ U.S. Food & Drug Administration, 510(k) *Third Party Review Program*, <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/510k-third-party-review-program> (last visited June 8, 2022).

legal advice,” and concluded that none of the communications at issue was privileged. (*Id.* at 7-8.)

Defendants assert that the Special Master utilized an incorrect legal standard in considering the communications. Defendants note that the attorney-client privilege “extends to agents of the attorney,” such as third-party consultants, “where the confidential communication was made for the purpose of assisting the attorney in rendering legal advice to the client,” *Graff v. Haverhill N. Coke Co.*, No. 1:09-CV-670, 2012 WL 5495514, at *15 (S.D. Ohio Nov. 13, 2012), and argue that it was not necessary for any third-party to provide legal advice for the attorney-client privilege to apply. Defendants contend that FDA Third Party Review Group was retained by Defendants to provide guidance regarding a “complex subject-matter[]” – namely SmileDirect’s 510(k) submission – and that the communications exchanged between the two are privileged on the basis that they were made in furtherance of counsel’s provision of legal advice to SmileDirect. (Docket No. 325 at 3, 5.)

Despite Defendants’ focus on the potential reach of the attorney-client privilege, the Court first addresses the Special Master’s conclusion that the communications between Defendants and FDA Third Party Review Group were not made pursuant to a common interest agreement, the existence of which is a prerequisite for the doctrine to apply. *See John B. v. Goetz*, 879 F. Supp.2d 787, 898 (M.D. Tenn. 2010) (“Defendants must prove an agreement among its members to share information arising out of a common legal interest in litigation.”) (citing *United States v. Moss*, 9 F.3d 543, 550 (6th Cir. 1993)). A written agreement is not required, although the parties claiming privilege must have “clearly and specifically agree[d] to the joint venture in some manner.” *Cooey v. Strickland*, 269 F.R.D. 643, 652–53 (S.D. Ohio 2010). *See also Minebea Co. v. Papst*, 228 F.R.D. 13, 16 (D.D.C. 2005) (“Obviously,

a written agreement is the most effective method of establishing the existence of a joint defense agreement, although an oral agreement whose existence, terms and scope are proved by the party asserting it, may be enforceable as well.”).

Defendants assert that they “retained the FDA Third Party Review Group to provide advice regarding [SmileDirect’s] 510(k) submission” (Docket No. 325 at 5), but their objection makes no reference to any agreement confirming the respective parties’ purported common legal interest. The documents provided to the Special Master for review include a “letter of authorization” that permits FDA Third Party Review Group to submit a 510(k) on Access Dental Lab’s behalf,⁴ as well as a contract indicating that FDA Third Party Review Group will perform “traditional 510(k) review” and maintain the confidentiality of certain proprietary information belonging to SmileDirect. But there is certainly no formal agreement memorializing an intent to “share information arising out of a common legal interest in litigation.” *Goetz*, 879 F. Supp. 2d at 898.

Additionally, the Court finds no merit in Defendants’ argument that the Special Master applied an incorrect legal standard. In context, the Special Master’s ruling clearly was not based on the fact that FDA Third Party Review Group did not directly provide legal advice to SmileDirect in this case, but rather that FDA Third Party Review Group does not assist in the provision of any legal advice given its status as an FDA-accredited entity that only reviews medical device submissions. The communications at issue in fact suggest that FDA Third Party Review Group is “more akin to the FDA itself,” as opposed to an independent consultant retained to provide legal advice. (Docket No. 319 at 7.) Emails from FDA Third Party Review Group identify SmileDirect as “applicant” and refer to timelines that must be met to avoid

⁴ Although not explained in any of the briefing, it appears that Access Dental Lab is a subsidiary of Defendant SmileDirect.

automatic withdrawal of an application. The fee normally charged by the FDA to any manufacturer seeking medical device product review is waived when, as here, the manufacturer relies on a third-party review group that in turn collects a fee for its services.⁵ FDA Third Party Review Group’s own website describes its role as reviewing medical device submissions “on behalf of the FDA as part of the Third Party Review Program.”⁶

Accordingly, the Court finds that the Special Master did not abuse his discretion in determining that the subject communications involving FDA Third Party Review Group were not protected by the attorney-client privilege. Defendants must provide such documents to Provider Plaintiffs within **14 days** of the date of entry of this order.

2. Ian Kitching

SmileDirect retained Ian Kitching as a consultant to assist with its 510(k) application. The Special Master, after reviewing Mr. Kitching’s engagement letter and a sampling of his communications with SmileDirect, found no basis for Defendants to claim attorney-client privilege. The Special Master highlighted the absence of any reference to “legal advice” or a common interest agreement in the engagement letter – which describes Mr. Kitching’s role as “render[ing] consulting services to the Company in connection with its 510K submission to the FDA and any and all related documentation, verification and validation in connection therewith” – and noted that Mr. Kitching’s emails included little more than “updates on the 510(k) application process.” (Docket No. 319 at 9.) The Special Master therefore ordered Defendants to turn over all of their communications with Mr. Kitching. (*Id.*)

⁵ Medical Device User Fees. <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/medical-device-user-fees> (last visited June 15, 2022.)

⁶ <https://fdathirdpartyreview.com/> (last visited June 15, 2022).

Defendants object to this portion of the order by arguing that Mr. Kitching’s input “related to strategic legal decisions” that SmileDirect’s counsel made. (Docket No. 325 at 5-6.) It is true that when an attorney employs outside consulting services, the attorney-client privilege may be “extended to such third parties employed to assist a lawyer in the rendition of *legal services*.” *Graff*, 2012 WL 5495514, at *15 (quoting *Abdallah v. Coca-Cola Co.*, No. CIV A1:98CV3679RWS, 2000 WL 33249254, at *3 (N.D. Ga. Jan. 25, 2000)) (emphasis added). While the communications at hand reveal that Mr. Kitching provided guidance with respect to SmileDirect’s 510(k) application, this was limited to regulatory compliance, which has been held to fall outside of the scope of attorney-client privilege. *See In re Nat’l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2020 WL 9211219, at *1 (N.D. Ohio Mar. 30, 2020) (noting that “compliance with regulations is usually a business matter, not a legal one”). While there may be authority to suggest otherwise, this does not render the Special Master’s ruling unreasonable. The Court thus finds that the Special Master did not abuse his discretion as to communications between Defendants and Ian Kitching. Defendants must provide such documents to Provider Plaintiffs within **14 days** of the date of entry of this order.

3. MRC-X and Knoell USA

Finally, the Special Master concluded that communications involving MRC-X and Knoell USA – both consultants retained by SmileDirect to assist with the 510(k) application – that were withheld by Defendants on the basis of attorney-client privilege must be produced. (Docket No. 319 at 12-13.) The Special Master found that the subject communications “do not contain legal advice ... [and] even if they were arguably privileged, a number of the communications include third parties that would otherwise destroy the privilege.” (*Id.* at 12.) He

further based his ruling on the failure of Defendants to provide any indication that they “entered into a common interest agreement or sought legal advice” from MRC-X or Knoell USA. (*Id.*)

Defendants object to this ruling on two grounds. First, they allege that because Provider Plaintiffs did not initially challenge Defendants’ claim that communications involving MRC-X and Knoell USA were privileged, Defendants were not given sufficient opportunity to “provide evidence regarding these entities” to the Special Master. (Docket No. 325 at 6.) Second, Defendants note that elsewhere in the order, the Special Master acknowledged that documents containing regulatory advice could be protected under the privilege if the primary purpose of the documents was “soliciting legal, rather than business, advice,” and that several of the communications he reviewed *in camera* “contain sufficient legal advice to protect them from disclosure.” (Docket No. 319 at 11.) It is therefore inconsistent, according to Defendants, for the Special Master to then hold that the same third-parties were not retained for assisting in the provision of legal advice when they were both retained by counsel and included on communications that either solicited or provided legal advice. (Docket No. 325 at 6.)

The Court finds no merit in the Defendants’ first argument. Provider Plaintiffs point to their portion of the joint discovery dispute statement that gave rise to the Special Master’s order requiring *in camera* review, in which Provider Plaintiffs specifically argued that communications involving regulatory or business advice were not protected by privilege and should be produced. (Docket No. 295 at 8.) Moreover, it is unclear how additional evidence relating to MRC-X or Knoell USA would benefit the Court’s analysis at this juncture given that these third-parties are very similar – if not identical – in status to consultant Ian Kitching, whose communications were reasonably found to exist beyond the purview of attorney-client privilege, as discussed above. And notably, Defendants do not suggest that they can produce proof of a preexisting common


interest agreement with MRC-X or Knoell USA, which formed at least part of the basis for the Special Master's ruling. (Docket No. 319 at 12.)

The Court similarly finds no abuse of discretion in the Special Master's finding that the communications at issue did not involve solicitation or provision of legal advice. Defendants rely on *In re Flonase Antitrust Litig.*, 879 F. Supp. 2d 454 (E.D. Pa. 2012), in which the presiding district judge held that a third-party consulting firm that played a "a crucial role ... assisting in an administrative, managerial, and analytic capacity" in a company's "brand maturation plan" was the functional equivalent of a company employee, and whose communications with the company could be protected by the attorney-client privilege. *Id.* at 460. However, the court noted that because it had not reviewed the documents in question, it was "impossible to know" whether the communications were created for the purpose of providing or obtaining legal advice and thus subject to protection by the privilege. *Id.*

In contrast, the Special Master reviewed the communications with MRC-X and Knoell USA at issue and concluded that they involved regulatory, and not legal, advice that is not protected by the attorney-client privilege. The Court has reviewed these documents and holds that the Special Master's conclusion as to the communications between Defendants and MRC-X and Knoell USA is not unreasonable. *See Fed. Trade Comm'n v. Abbvie, Inc.*, No. CV 14-5151, 2015 WL 8623076, at *9 (E.D. Pa. Dec. 14, 2015) (holding that the attorney-client privilege "does not apply if the client seeks regulatory advice for a business purpose") (internal citations omitted). The Court therefore finds no abuse of discretion. Defendants must provide the documents in question to Provider Plaintiffs within **14 days** of the date of entry of this order.

In summary, for the foregoing reasons, Defendants' Objection (Docket No. 325) is OVERRULED and Defendants must produce the documents in question to Provider Plaintiffs within 14 days of the date of entry of this order.

It is SO ORDERED.


BARBARA D. HOLMES
United States Magistrate Judge